

FILED ELECTRONICALLY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 09/894,984 Confirmation No.: 3805
Applicant : Stephen D. Ainsworth, et al.
Filed : June 28, 2001
Title : LOW PROFILE STENT WITH FLEXIBLE LINK
Art Unit : 3738
Examiner : Suba Ganesan

Docket No.: : ACS-55940 (G2645US01)
Customer No. : 24201 September 19, 2007

DECLARATION OF PRIOR INVENTION IN THE UNITED STATES
TO OVERCOME CITED PATENT OR PUBLICATION
UNDER 37 C.F.R. § 1.131

Commissioner for Patents
Washington, D.C. 20231

I, Andreina P. Gomez, declare the following:

1. I am one of the inventors of the subject matter of pending claims 1-8 and 10-20 of the above-identified patent application.
2. I submit this declaration in support of the above-identified patent application, and specifically to traverse the 35 U.S.C. § 102 (e) rejection held by the Examiner in an Office Action dated July 27, 2007. The Examiner cited U.S. Patent No. 6,790,227 to Burgermeister (the "Burgermeister patent") to support the grounds for rejection. I have read the Office Action and the Burgermeister patent.

3. I submit this declaration with the response to the July 27, 2007 Office Action for the purpose of overcoming the grounds of rejection based on the Burgermeister patent. The present application was filed on June 28, 2001.

4. The invention of the pending claims of the present application is fully disclosed in the present application. We completed the invention covered by the claims of the pending application in the United States at a date prior to March 1, 2001, which is the effective date of the Burgermeister patent. We were diligent in reducing the invention to practice from the time of conception, to a time just prior to the date of the reference, up to the filing of the parent application.

5. To establish the date of completion in the United States of the invention, I submit the following document attached hereto as evidence:


Exhibit A is an invention disclosure form submitted by me and my co-inventor and co-signed by my colleague describing the concepts of our invention. This form was forwarded to an in-house patent evaluation committee. All signatures on this form were dated before the March 1, 2001 effective date of the Burgermeister patent.

6. I declare that the attached Exhibit A is a true and accurate copy of an actual document in the files of Advanced Cardiovascular Systems, Inc., the assignee of the present application, except that the dates in Exhibit A have been redacted as permitted under M.P.E.P. Rule 715.07.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United

States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of inventor: ANDREINA P. GOMEZ

Inventor's signature: 

Date: September 18, 2007

Residence: Santa Clara, California

Citizenship: Venezuela

Post Office Address: ~~3560 Flora Vista #328~~ 21695 COMITA AVE
~~Santa Clara, CA 95051~~ CUPERTINO, CA 95014

EXHIBIT A

GUIDANT CONFIDENTIAL & PRIVILEGED

For Legal Department Use Only

Docket No.: 2645

Date Assigned:

Date Discl. Rec'd:

Stent


INVENTION DISCLOSURE FORM

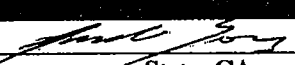
ADVANCED CARDIOVASCULAR SYSTEMS, INC.


This is a form for disclosing ideas and inventions to the Guidant VI Legal Department for patent consideration. This form may be used before experimental work has been done. While some of the requested information may not be available at this time, include as much information as you can about the invention. Attach additional sheets if necessary, and sign and date each sheet. Additional information will be requested later.

Please complete each indicated area and return to Intellectual Property Paralegal, Guidant Vascular Intervention Group, 3200 Lakeside Drive, M/S S314, Santa Clara, CA 95052, and a copy to the R&D Director.

1. DESCRIPTIVE TITLE OF THE INVENTION: Low profile stent with flexible link**KEY WORDS:** stent, intravascular**2. Submitter(s): (please provide your full name, including middle name)**

Full Name: Stephen D. Ainsworth		Signature: 	
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Empl. No. 020940	Division Name: VI	Manager Name: Patricia Gray	

Full Name: Andreina P. Gomez		Signature: 	
Home address: 3560 Flora Vista #328	City: Santa Clara	State: CA	Zip: 95051
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Empl. No. 018972	Division Name: VI	Manager Name: Jon Becker	

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Citizenship:		Home phone no.:	
Work no.:		Work fax no.:	
Empl. No.	Division Name:	Manager Name:	

Full Name:		Signature:	
Home address:	City:	State:	Zip:
Citizenship:		Home phone no.:	
Work no.:		Work fax no.:	
Empl. No.	Division Name:	Manager Name:	

If there are more than 4 inventors, use the additional page at the end of this document.

Inventors initials:

1  2 AG 3 _____ 4 _____ 5 _____ 6 _____ 7 _____ 8 _____ 9 _____

To which division or operation does this invention best apply? Vascular Intervention	
Field of Technology: Stents	
Related Invention Disclosure Docket Nos.:	
Project Name/Description: WH02/SVS02/stent	
Product Name:	
Estimated/actual manufacturing release date of invention or product incorporating or using the invention: (date)	
Estimated/actual date of offer for sale of product incorporating or using the invention: (date)	

(a) Describe the invention in as much detail as possible, and include a description of a working prototype, if any. Write your description using reference numerals placed on a drawing. Point out and explain relationship with associated equipment. (b) How is the invention used? (c) How does it relate to present or potential commercial products of the company or others? (d) State the significance of the invention, and any problems it is intended to solve. Please supplement when possible by attaching sketches, engineering drawings, pages from lab books, photographs, and the like.

The stent pattern described in this disclosure represents a pattern that is based on ACS Multilink, ACS Multilink Tetra and ACS Multilink Penta. The stent pattern used for the ACS Multilink Penta incorporates a flexible link within the ring width of the stent as seen in Pattern P56 on page 95 of Lab Notebook No.5558 (attachment 1). The problem with adding this link to the ACS Multilink type pattern is that it prohibits the ability of the stent to crimp to a very low profile. By shortening three of the six bar-arm-crown combinations, it is possible to embed the flexible and adaptable link within the ring width and still be able to crimp the stent to a much lower profile.

Attachment 2 shows a sketch of both the normal P56 type pattern (Penta) and the shortened crown pattern. Attachment 3 shows a possible pattern that embodies the above idea and represents the as cut geometry of the stent.

Describe the invention in terms of the *broadest* generic scope which you expect will be operable (e.g. if a machine or article, describe alternate type and sizes of materials for construction, etc.; if a process, describe alternate manufacturing conditions, etc.)

The invention can be used on any stent made out of any material to enable a stent to crimp to a smaller profile.

Has a literature search been made? Yes _____ No ☒ Don't know

If "Yes", list and if possible, attach copies of all literature, publications, patents and applications of which are relating to the invention. See section in Guidelines for Completing Invention Disclosure Form concerning obligation of disclosure.

Is this invention an improvement of an existing company product? Yes ☒ No _____ Don't know

If "Yes" identify the product:

ACS Multilink, ACS Multilink Solo, ACS Multilink Tetra, ACS Multilink Penta

List the closest known prior art/technology: ACS Multilink

What is the current stage of development of the invention?

Prototypes have been through several series of tests

Has a description been published or is it scheduled to be published?

Yes _____ No ☒ Don't know

Has a description been disclosed or is it scheduled to be disclosed outside of Guidant?

Yes _____ No ☒ Don't know

If "Yes", when and to whom?

Was a Non-Disclosure Agreement used? Yes _____ No _____ Don't know

If "Yes", please attach a copy of the agreement to the disclosure.

Inventors initials:

1 SA 2 AG 3 _____ 4 _____ 5 _____ 6 _____ 7 _____ 8 _____ 9 _____

GUIDANT CONFIDENTIAL & PRIVILEGED

Was this invention made under a government agency contract?

Yes _____ No ☒ Don't know

If "Yes":

List all non-Guidant inventors:

List all government contract numbers:

Read and understood the completed Invention Disclosure Form

Brent S. Belding
Printed Name

Brent S. Belding
Signature Date

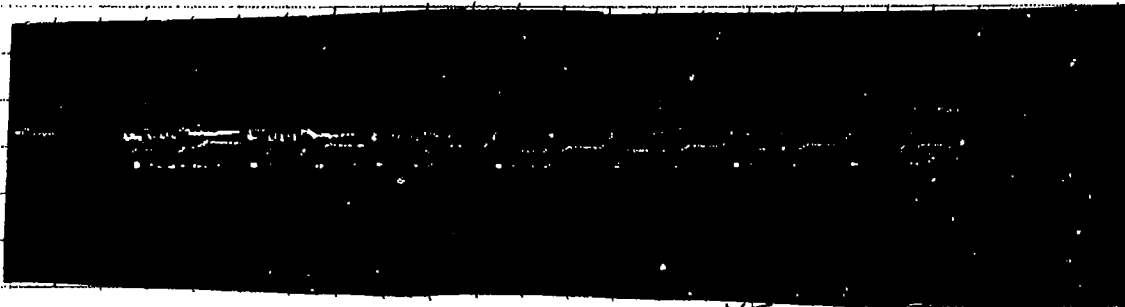
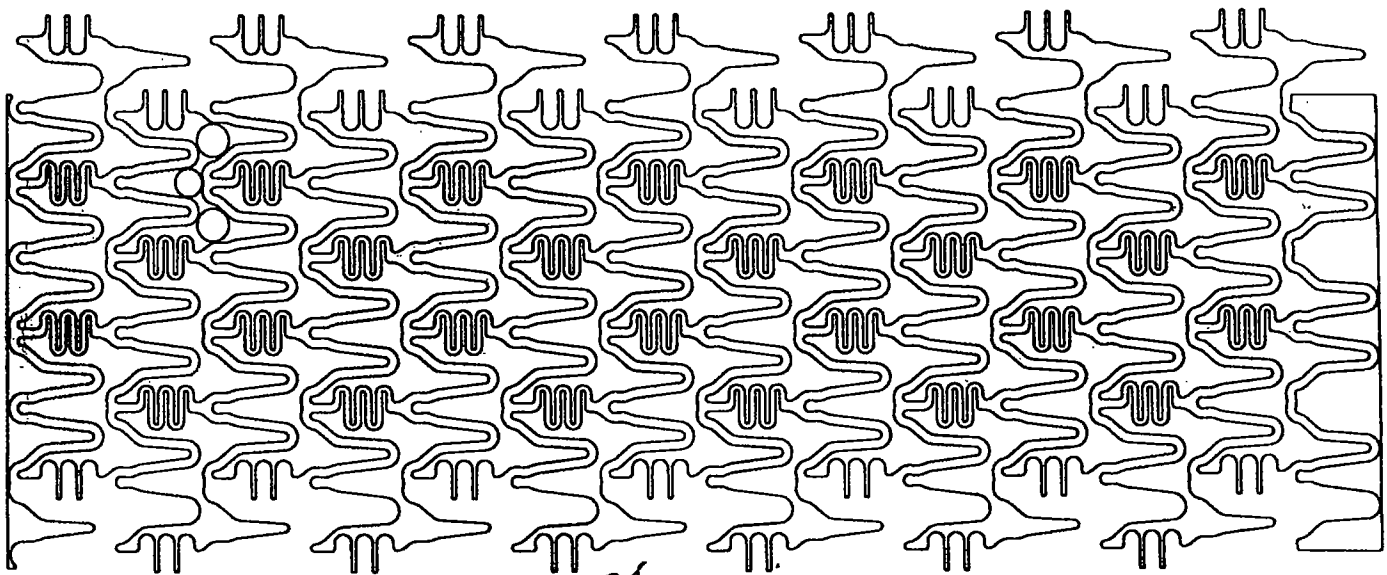
Inventors initials:

1 SB 2 AG 3 _____ 4 _____ 5 _____ 6 _____ 7 _____ 8 _____ 9 _____

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P56 Pattern

- Pattern P42 worked very well, but the unsupported surface area was fairly large.
- In an attempt to increase the unsupported surface area while gaining flexibility, more turns were included in the "M" link and the bar arms were shortened to be similar to tetra in length.

Crimped P56

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DATE

WITNESS

DATE

DATE

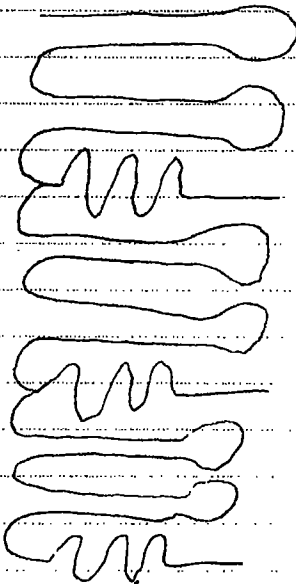
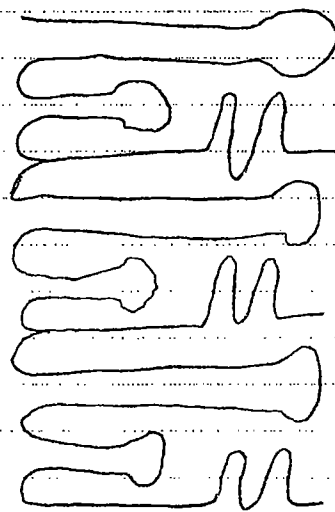
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Title: Low profile stent with flexible link.

Background: The stent pattern used for the MI Penta incorporates a flexible link within the ring width of the stent as seen in Pattern P56 on Page 95 of this Notebook. The problem with adding this link to the Multitube type pattern is that it prohibits the ability of the stent to crimp to a tight profile.

Pattern Idea: By shortening 3 of the 6 crowns in this design and lengthening (if needed) the other 3 crowns, we are able to embed the flexible link within the ring width still, and also crimp the stent to a much lower profile.

Normal P56 type
PatternShortened Crown
Pattern

This type pattern allows a much tighter crimped profile than the other one.

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DATE

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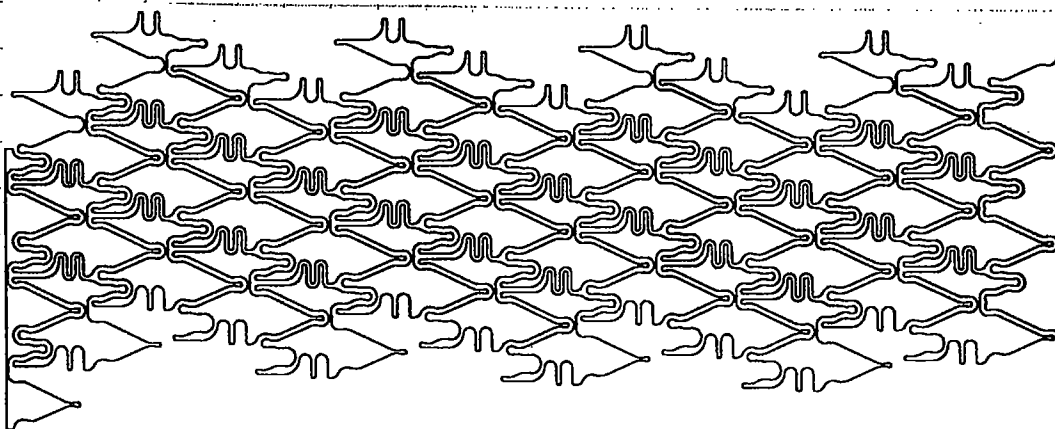
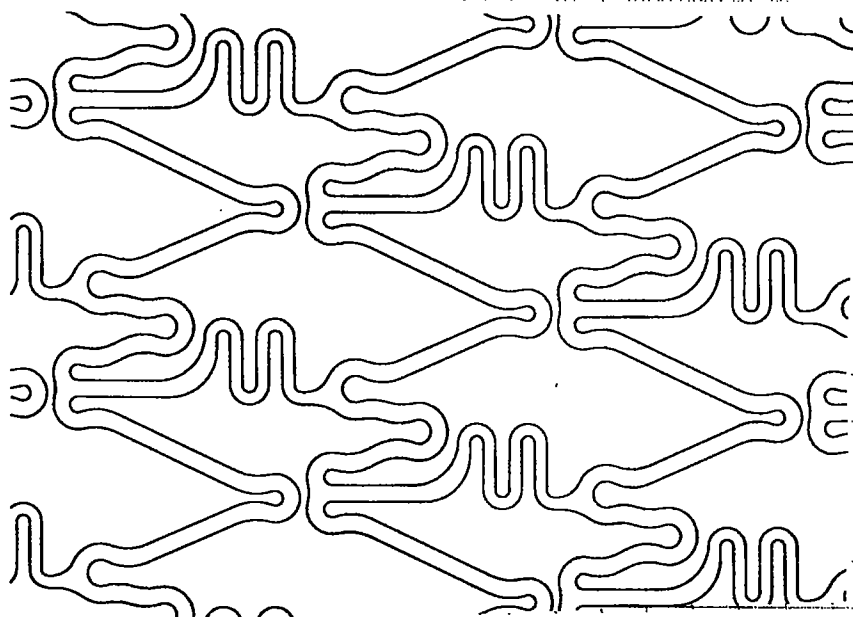
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The figure below shows a possible pattern that embodies this idea. The pattern represents the "as-cut" geometry



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